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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re Pfizer Hospital Products Group, Inc.	:	DECISION ON REQUEST
U.S. Patent No. 4,621,638	:	FOR RECONSIDERATION
	:	

A request for reconsideration was filed on September 19, 1991, by the patent owner of U.S. Patent No. 4,621,638 requesting that the Patent and Trademark Office (PTO) reconsider its decision dated April 17, 1991, holding that the patent is not eligible for patent term extension under 35 USC § 156. The patent owner further requests the PTO to determine that the product claimed in the patent was subject to a "regulatory review period" within the meaning of 35 USC § 156 (a)(4) and that the patent is therefore eligible for extension of its term under 35 USC § 156.

An application for extension of the term of the patent, which claims a product drawn to a medical device, was filed in the PTO by the patent owner Pfizer Hospital Products Group, Inc. (Pfizer) on February 22, 1991. The medical device claimed in the patent is the Dekantel Microflex Ophthalmic Suture (a non-absorbable polypropylene suture). In its application, Pfizer asserts that the suture was subject to a regulatory review period. The suture was originally classified by the Food and Drug Administration (FDA) as a Class III medical device which is subject to approval by the FDA under section 515 of the Federal Food, Drug and Cosmetics Act (FFDCA), and subsequently reclassified as a Class II medical device which is subject to regulatory review for marketing by the FDA under section 510 (k) of the FFDCA. The suture was originally assigned to Class III as a "transitional device" which was regulated as a new drug prior to 1976. Accordingly, the suture was subject to FDA premarketing approval as a Class III device and Pfizer filed an Investigational Device Exemption (IDE) which was approved by the FDA on March 11, 1988. During the time the human clinical studies were being conducted under the IDE, the FDA, on July 5, 1990, reclassified this type of suture material as a Class II device. In view of the reclassification, at the conclusion of the clinical studies Pfizer filed a section 510 (k) application seeking permission to market the suture instead of a section 515 application seeking FDA approval of the suture. The FDA granted Pfizer permission to market the suture under section 510 (k) on December 12, 1991. In the letter granting the permission, the FDA stated that it did not mean that the FDA "approved" the suture.

The PTO decision of April 17, 1991, concluded that the patent was not eligible for patent term extension under 35 USC § 156 because the suture, a medical device, had not been subject to a "regulatory review period" within the meaning of section 156 (a)(4) which provides:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if - ...
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use; ... (emphasis added).

With respect to a medical device product, the "regulatory review period" is defined in section 156 (g)(3) as follows:

> (A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) ...
>
> (B) The regulatory review period for a medical device is the sum of - -
>
> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515 (f)(5) and ending on the date the protocol was declared completed under section 515 (f)(6) (emphasis added).

The reference to section 515 relates to section 515 of the FFDCA. 35 USC § 156 (f)(4). In its decision of April 17, 1991, denying the application for patent term extension, the PTO held that both subsections (i) and (ii) must be satisfied and that because an application under section 515 was not filed, neither subsection had been satisfied. Accordingly, the PTO concluded that the patent was not eligible for patent term extension because the suture had not been subject to a "regulatory review period" within the meaning of 35 USC § 156 (a)(4).

In its request for reconsideration, Pfizer acknowledges that the regulatory review of the suture, which initially began under section 515, did not include submission of an application under section 515 as the end of the testing phase and the beginning of the approval phase. Pfizer argues that this is because the reclassification of the suture from Class III to Class II by the FDA, over which Pfizer had no control, precluded the filing of such an application. Pfizer notes that more than two years of clinical trials were conducted as part the testing phase before the reclassification of the suture. Pfizer argues:

> [s]uch testing involved the effort and expense (and, of course, the inability to market the device) which is attendant to human clinical trials under Section 515, and that is exactly the delay for which Congress intended compensation by patent term extension.
>
> Awarding relief to Pfizer under the unique circumstances presented here is consistent with the broad remedial purposes of 35 U.S.C. § 156. (Recon., p.3).

In support of its argument, Pfizer relies upon the legislative history of the statute as noted in the House Report No. 98-857, Part I, 98th Cong., 2d Sess. 26 (1984) at page 2648:

> The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the lost time on patent life while the product is awaiting premarket approval. Under current law, a patent continues to run while the maker of the product is testing and awaiting approval to market it.

Pfizer argues the relief requested is consistent with the stated objectives of the legislation and that the delay in marketing which Pfizer suffered during the clinical investigation was exactly the relief contemplated by Congress. Pfizer urges that if Congress did not specifically consider the unique facts of this case, the remedial purpose of the statute and the intent of the legislature must govern.

As an alternative basis for relief, Pfizer requests that the testing phase of the regulatory review which started under section 515 be considered terminated as of the effective date of the reclassification of the suture from a Class III device to a Class II device, and that no approval period be credited to the extension period. Under this alternative, only the actual delay which occurred during the testing phase under section 515 would be measured.

Pfizer cannot prevail on its arguments that its patent is eligible for patent term extension merely because the claimed medical device underwent regulatory review under section 515 for a period of over two years before being reclassified as a Class II device and subsequently approved under section 510 (k). The patent term extension statute is not intended to compensate all patent owners for time lost during regulatory review of a product covered by a patent, nor to fully compensate a patent owner for all of the time "lost" during regulatory review of a product. While some time may have been "lost" due to the initial regulatory review of the suture under section 515 prior to its reclassification, Pfizer is not entitled to receive an extension of the term of its patent to recover any of this time because this time does not qualify as a "regulatory review period" as defined by the statute.

The starting point for statutory interpretation is the plain language of the statute. Unless it is ambiguous, the language Congress chose is conclusive of its meaning absent a clearly stated contrary intention. Burlington Northern R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987). See also Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 395; 13 USPQ2d 1628, 1630 (Fed. Cir. 1990) (absent a "clearly expressed legislative intention to the contrary," a statute's plain meaning "must ordinarily be regarded as conclusive"). The plain language of the statute is crystal clear. It clearly states that the regulatory review period for a medical device under section 156 (g)(3)(B) is the sum of the periods defined by subsections (i) and (ii). Subsection (i) requires a clinical investigation of the device on humans which ends on the date an application is filed under section 515. Subsection (ii) requires either that an application be filed under section 515, or that a product development protocol be submitted under section 515 (f)(5). There is no mention of section 510 (k). Therefore, section 156 (g)(3)(B) admits of no other meaning than that the testing period ends with the filing of a section 515 application and that the approval stage begins with the filing of a section 515 application. Since a section 515 application was not filed with the FDA during regulatory review of the suture, neither of these requirements have been satisfied. Acceptance of Pfizer's view would read important language out of the statute. But one "must give effect, if possible, to every word of the statute." Bowsher v. Merck & Co., 460 U.S. 824, 833 (1983). Accordingly, the regulatory review for the suture, partly under section 515 and partly under section 510 (k), does not satisfy the requirements of section 156 (a)(4).

The statements in the legislative history, on which Pfizer relies, fail to provide the clearly expressed legislative intention, contrary to the statutory language, necessary to avoid the conclusive effect of the statute itself. Pfizer makes what can only be characterized as policy arguments pointing to lofty

goals indicating that Congress broadly sought to encourage innovation by enacting the 1984 Act. However, it is the express language of the statute at issue, in addition to the direct discussions of specific provisions, and not broad statements of lofty goals that constitute the proper source of interpretation of this complex statutory provision. Fisons plc v. Quigg, 8 USPQ2d 1491,1500 (DDC 1988); affm'd 876 F2d 99, 101; 10 USPQ2d 1869, 1871 (Fed. Cir. 1989).

Pfizer cannot prevail on its alternative request for relief. The reclassification of the suture by the FDA as a Class II device cannot be used as a substitute for the filing of a section 515 application for the same reasons the filing of a section 510 (k) application cannot satisfy the requirements of section 156 (g)(3)(B).

For all of the reasons set forth above, the request for reconsideration is denied.

C. E. Van Horn

Date: 22 March 1993

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

John L. LaPierre
Pfizer Inc.
Patent Dept., 20th Floor
235 East 42nd Street
New York, NY 10017 - 5755

(For Patent Owner)

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: Dekantel Microflex
Ophthalmic Suture

FDA Docket No. 91E - 0091